U.S. Food and Drug Administration

# Over-the-Counter (OTC) Monograph M011: Stimulant Drug Products for Over-the-Counter Human Use (Posted October 14, 2022)[1]

## Part A—General Provisions



## Part B—Active Ingredients



## Part C—Labeling



SOURCE: 53 FR 6105, Feb. 29, 1988, unless otherwise noted.

## Part A—General Provisions

### § M011.1 Scope

An over-the-counter (OTC) stimulant drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this OTC monograph and each of the general conditions established in 21 CFR 330.1.

### § M011.3 Definition

As used in this OTC monograph:

Stimulant. A drug which helps restore mental alertness or wakefulness during fatigue or drowsiness.

---

[1] Final Administrative Order (OTC000025), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

## Part B—Active Ingredients

### § M011.10 Stimulant active ingredient

The active ingredient of the product consists of caffeine when used within the dosage limits established in § M011.50(d).

### § M011.20 Permitted combinations of active ingredients

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the product is labeled in accordance with § M011.60.

Combinations containing a single stimulant active ingredient and a single internal analgesic active ingredient. [See § M013.20(b)(5) of OTC Monograph M013.]

[56 FR 66758, Dec. 24, 1991]

## Part C—Labeling

### § M011.50 Labeling of stimulant drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "alertness aid" or a "stimulant."

(b) Indications. The labeling of the product states, under the heading "Uses," the following: "Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M011.50(b) may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

> (1) "The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat."
>
> (2) "For occasional use only. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a" (select one of the following: "physician" or "doctor").

(3) "Do not give to children under 12 years of age."

(d) Directions. The labeling of the product contains the following information under the heading "Directions": Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.

**§ M011.60 Labeling of permitted combinations of active ingredients**

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) Statement of identity. For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs.

(b) Indications. The labeling of the product states, under the heading "Uses," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC monographs unless otherwise stated in § M011.60(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M011.60(b) may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the FD&C Act relating to misbranding and the prohibition in section 301(d) of the FD&C Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act.

(1) For permitted combinations containing a stimulant and an internal analgesic active ingredient identified in § M011.20(a). The indications in § M013.60(b)(6) of OTC Monograph M013 should be used.

(c) Warnings. The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the Warnings sections of the applicable OTC monographs, unless otherwise stated in § M011.60(c).

(1) For permitted combinations containing any stimulant ingredient identified in § M011.20. The following warning should be used instead of the warnings in § M011.50(c)(2) and § M013.50(c)(1) of OTC Monograph M013: "For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a" (select one of the following: "physician" or "doctor").

(d) Directions. The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC monographs unless otherwise stated in § M011.60(d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

[56 FR 66758, Dec. 24, 1991]